Comparison of Two Treatment Regimens for Helicobacter pylori Eradication in Lebanon

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Main Information

Primary registry identifying number

LBCTR2024095653

Protocol number

H.pylori-2016-001

MOH registration number

NA

Study registered at the country of origin

Yes

Study registered at the country of origin: Specify

Type of registration

Retrospective

Type of registration: Justify

The trial is being registered retrospectively to ensure transparency and contribute to scientific knowledge, as initial efforts focused on ethical approvals and study implementation.

Date of registration in national regulatory agency

Primary sponsor

Holy Spirit University of Kaslik (USEK), School of Medicine and Medical Sciences.

Primary sponsor: Country of origin

Lebanon

Date of registration in primary registry

17/10/2024

Date of registration in national regulatory agency

Public title

Comparison of Two Treatment Regimens for Helicobacter pylori Eradication in Lebanon

Acronym

CTBQT-H. pylori

Scientific title

A Randomized Prospective and Crossover Study Comparing the Eradication Rate After 10 Days of Concomitant Therapy to Bismuth Quadruple Therapy Among a Sample of the Lebanese Population

Acronym

RCT-COMP-BQT

Brief summary of the study: English

This study aimed to compare the effectiveness of two treatment regimens, concomitant therapy and bismuth quadruple therapy, for the eradication of *Helicobacter pylori* among a sample of the Lebanese population. It was a randomized, prospective, and crossover study conducted between 2016 and 2018. Patients with active *H. pylori* infection were divided into two groups and treated with either regimen for 10 days. The eradication success was assessed using the 14C urea breath test. Both therapies were found to be equally effective as first-line treatments, but concomitant therapy showed higher efficacy when used as a second-line treatment.

Brief summary of the study: Arabic

تهدف هذه الدراسة إلى مقارنة فعالية نظامي علاج، العلاج المتزامن والعلاج الرباعي المحتوي على البزموت، في استئصال جرثومة *Helicobacter pylori* بين عينة من السكان اللبنانيين. كانت الدراسة عشوائية، استباقية، ومتقاطعة أجريت بين عامي 2016 و2018. تم تقسيم المرضى المصابين بعدوى *H. pylori* النشطة إلى مجموعتين وتلقوا أحد النظامين العلاجيين لمدة 10 أيام. تم تقييم نجاح الاستئصال باستخدام اختبار التنفس باليوريا 14C. أظهرت النتائج أن كلا النظامين كانا فعالين بالتساوي كعلاج أولي، بينما أظهر العلاج المتزامن فعالية أعلى عند استخدامه كعلاج ثان.

Health conditions/problem studied: Specify

The health condition/problem studied in this trial is **Helicobacter pylori infection**, which is associated with gastrointestinal disorders such as

gastritis, peptic ulcers, and an increased risk of gastric cancer and MALT lymphoma.

Interventions: Specify

The interventions in the study were two treatment regimens for the eradication of *Helicobacter pylori*:

1. **Concomitant Therapy**: A 10-day regimen consisting of esomeprazole 40 mg twice daily, amoxicillin 1 g twice daily, clarithromycin 500 mg twice daily, and metronidazole 500 mg twice daily.

2. **Bismuth Quadruple Therapy**: A 10-day regimen consisting of esomeprazole 40 mg twice daily, along with a capsule containing bismuth, tetracycline, and metronidazole (3 capsules taken four times a day).

Patients who did not achieve eradication with the first treatment were switched to the other therapy.

Key inclusion and exclusion criteria: Inclusion criteria

The inclusion criteria for the study were:

1. **Positive Helicobacter pylori infection** confirmed through histological findings.
2. **No prior eradication therapy** for *Helicobacter pylori*.
3. **Written informed consent** provided by all participants.

These criteria ensured that the study focused on patients with active *H. pylori* infections who had not undergone previous treatment.

Key inclusion and exclusion criteria: Gender

Both

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age minimum

18

Key inclusion and exclusion criteria: Age maximum

75

Key inclusion and exclusion criteria: Exclusion criteria

The exclusion criteria for the study were as follows:

1. **Recent exposure to antibiotics**.
2. **History of allergy or intolerance** to any of the components in the treatment regimens.
3. **Presence of gastric cancer** confirmed by histological findings.
4. **Patients who had undergone prior eradication therapy** for *Helicobacter pylori*.

These criteria ensured the exclusion of patients who might have confounding factors affecting treatment outcomes or safety.

Type of study

Observational

Type of intervention

N/A

Type of intervention: Specify type

N/A

Trial scope

N/A

Trial scope: Specify scope

N/A

Study design: Allocation

N/A

Study design: Masking

N/A

Study design: Control

N/A

Study phase

N/A

Study design: Purpose

N/A

Study design: Specify purpose

N/A

Study design: Assignment

N/A

Study design: Specify assignment

N/A

IMP has market authorization

IMP has market authorization: Specify

Name of IMP

Year of authorization

Month of authorization

Type of IMP

Pharmaceutical class

Therapeutic indication

Therapeutic benefit

Study model

Case-Crossover

Study model: Specify model

N/A

Study model: Explain model

It included a crossover component, where patients who did not respond to the initial treatment were switched to the alternative therapy and re-evaluated.

Time perspective

Prospective

Time perspective: Specify perspective

N/A

Time perspective: Explain time perspective

It was prospective, meaning data were collected as the study progressed.

Target follow-up duration

6

Target follow-up duration: Unit

weeks

Number of groups/cohorts

2

Biospecimen retention

None retained

Biospecimen description

NA

Target sample size

427

Actual enrollment target size

374

Date of first enrollment: Type

Actual

Date of first enrollment: Date

01/03/2016

Date of study closure: Type

Actual

Date of study closure: Date

01/12/2018

Recruitment status

Complete

Recruitment status: Specify

Date of completion

31/12/2018

IPD sharing statement plan

No

IPD sharing statement description

NA

Additional data URL

NA

Admin comments

Trial status

Approved

Secondary Identifying Numbers

No Numbers

Sources of Monetary or Material Support

No Sources

Secondary Sponsors

No Sponsors

Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Jad Chidiac	Paris	France	0763918897	jad_chidiac@live.com	USEK
Scientific	Charbel Yazbeck	Jbeil	Lebanon	03334998	charbelyazbeck@usek.edu.lb@live.com	USEK

Centers/Hospitals Involved in the Study

No Centers/Hospitals

Ethics Review

No Reviews

Countries of Recruitment

Name
Lebanon

Health Conditions or Problems Studied

No Problems Studied

Interventions

No Interventions

Primary Outcomes

No Outcomes

Key Secondary Outcomes

No Outcomes

Trial Results

Summary results

Study results globally

Date of posting of results summaries

Date of first journal publication of results

Results URL link

Baseline characteristics

Participant flow

Adverse events

Outcome measures

URL to protocol files